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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|----------------------|--------------------------|----------------------|---------------------|------------------|--|
| 10/674,279 | 09/29/2003 | Wolfgang Hartung | 117163.00090 | 3123 | |
| 21324 | 7590 12/15/2005 | | EXAMINER | | |
| HAHN LOES | HAHN LOESER & PARKS, LLP | | | ALTER, ALYSSA M | |
| One GOJO Pla | aza | | | <u> </u> | |
| Suite 300 | Suite 300 | | ART UNIT | PAPER NUMBER | |
| AKRON, OH 44311-1076 | | | 3762 | | |

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | |
|---|--|-------------------|--|--|--|
| Office Action Octo | 10/674,279 | HARTUNG, WOLFGANG | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| · | Alyssa M. Alter | 3762 | | | |
| The MAILING DATE of this communication app Period for Reply | • | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | |
| Status | | | | | |
| 1) Responsive to communication(s) filed on 02 Ju | ily 2004. | | | | |
| 2a) ☐ This action is FINAL . 2b) ☑ This | | | | | |
| Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | |
| 4) ☐ Claim(s) 1-26 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-26 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement. | | | | | |
| Application Papers | | | | | |
| 9) ☐ The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 02 July 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) □ All b) □ Some * c) ⊠ None of: 1. □ Certified copies of the priority documents have been received. 2. ☒ Certified copies of the priority documents have been received in Application No. DE 102 45 852.9. 3. □ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/2/04 | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | | | | |

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 1-7 and 11-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, which renders these claims non-statutory.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 3-5 and 11-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 3 and 11, the examiner is unsure if the two or more floating electrodes are in addition to the one electrode as claimed in claim 1 or inclusive of the electrode. The examiner recommends changing claim 1, from "an electrode arranged floatingly" to --at least one electrode arranged floatingly--.

As to claims 4 and 12-13, the examiner is unsure if the single wall-located electrode is in addition to the other single wall-located electrode as claimed in claim 1 or inclusive.

If it is inclusive, the further recitation of a single wall-located electrode fails to further limit the previous claim since claim 1 already recites a wall-located electrode. As a result, the claims 4 and 12-13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

As to claims 5 and 14-16, the claims are vague and it is unclear which structure performs the claimed function. Furthermore, the "switching over" recited in the claim is only inferentially included and needs to be positively cited.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 1. Claims 1, 3-9 and 11-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson et al. (US 5,846,263). Peterson et al. discloses an implantable pacemaker for the diagnosis and treatment of arrythmias. The implantable medical device, or pacemaker, can be seen in figure 1. The examiner considers the extendable helix electrode 17, to be the wall-located electrode and the ring electrode 21 to be the floating electrode. "Electrodes 17 and 21 are employed for atrial pacing and for sensing atrial depolarizations" (col. 3, lines 24-25). Therefore the electrodes are both stimulating and sensing electrodes.

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As to claims 3 and 11, the examiner considers the elongated coil electrode 23, which is proximal to electrode 21 on the atrial/SVC lead, to be the additional floating electrode. Alternatively, the examiner also considers the uninsulated portion of the housing 11, which serves an as subcutaneous defibrillation electrode to defibrillate either the atria or ventricles, to be an additional floating electrode.

As to claim 9, a "switch matrix 208 is used to select which of the available electrodes are coupled to wide band (0.5-200 Hz) amplifier 210 for use in digital signal analysis" (col. 4, lines 48-50).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 1. Claims 2, 10 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson et al. (US 5,846,263). Peterson et al. discloses the claimed invention but does not disclose expressly the stimulation cycle length between 30 and 100 ms. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the stimulation as taught by Peterson et al., with the stimulation cycle length between 30 to 100 ms, because Applicant has not disclosed this stimulation cycle range provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the

Applicant's invention to perform equally well with stimulation as taught by Peterson et al., because the electrical stimulation by Peterson et al. is capable of terminating or treating arrhythmias.

Therefore, it would have been an obvious matter of design choice to modify stimulation to obtain the invention as specified in the claim(s).

Furthermore, Peterson et al. discloses the claimed invention except for the stimulation cycle length between 30 and 100 ms. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation cycle length, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re-Aller*, 105 USPQ 233 (see MPEP 2144.05).

Specification

1. The disclosure is objected to because of the following informalities: "——-" the large dash is often misplaced or ill suited in the specification. Since the specification is a literal English translation, there are several grammatical errors. Appropriate correction is required.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 9/30/02. It is noted, however, that applicant has not filed a certified copy of the 102 45 852.9 application as required by 35 U.S.C. 119(b).

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's

disclosure. van Groeningen (US 5,876,422) discloses a pacemaker that monitors atrial

signals and switches to asynchronous pacing with detected episodes.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-

4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Alyssa M Alter

Examiner

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JEFFREY P. JASTRZAE PRIMARY EXAMINER

12/12/05